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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,281	07/24/2003	Norman Milstein	U 0113 NHG/VEPT	1867

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EXAMINER	
SOLOLA, TAOFIQ A	
ART UNIT	PAPER NUMBER

1626

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,281	MILSTEIN, NORMAN	
	Examiner	Art Unit	
	Taofiq A. Solola	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-40 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

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Claims 1-40 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 33-35 are written in functional language and therefore, broader than the enabling disclosure. Therefore, claims 1-40 are indefinite. For example, claim 1 recites "providing" and "purifying" in steps (a) and (b). The claims must recite how one of ordinary skill in the art would perform the "providing", "purifying" and "separating" (claim 34). The claims must recite the reagents, the reaction times, pH, and reaction conditions that are involve in the steps. Applicant may not claim all processes of "providing", "purifying" and "separating" that are applicable in the instant invention, known and yet to be developed. Applicant must claim only the processes of "providing"; "purifying" and "separating" that embody applicant's invention. If the provided compounds are starting material they should be so indicated as in claim 34 step (a). The "solvent" in line 3, claim 16, is a critical element of the invention and therefore, must be identified. The "reducing agent" in claim 35 is a critical element of the step and therefore, must be identified.

A claim must stand alone to define the inventions, and incorporation into the claims by reference to the specification or an external source is not permitted. Ex parte Fressola, 27 USPQ 2d 1608, BdPatApp & Inter. (1993). In patent examination, it is essential for claims to be

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precise, clear, correct, and unambiguous. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

The term "comprises" in line 2 of claims 4, 6-8, 10, 12-15, 18-19, 21, 23-24, 26-27, 29, 30 renders the claims indefinite. The term is an open-ended term and cannot be used in referring to or describing a compound. By replacing the term with "is" the rejection would be overcome.

In line 2, claim 17, the term is used in reference to "filtration", which is a specific act. By replacing the term with "is by" the rejection would be overcome.

Claim 34 is rejected for being a substantial duplicate of claim 1. Under US patent practice substantial duplicate claims cannot be in the same application. By deleting claim 34 the rejection would be overcome.

Claims 38-40 are duplicates of claim 36. The claims are drawn as product-by process claims. However, under US patent practice, patentability of a product-by-process claim is based on the product itself though, the claims are limited and defined by their process of making. For example, see *In re Thorpe*, 227 USPQ 964 (CAFC, 1985). See also *Ex parte Gray*, 10 USPQ 2d 1922. By deleting claims 38-40 the rejection would be overcome.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1626

October 27, 2004